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July 24, 2006

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Mail Stop: Amendment

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Re:

U.S. Utility Patent Application

Application No. 10/698,928; Filed: October 31, 2003 For: Novel Cytarabine Monophosphate Prodrugs

Inventors:

Boyer et al.

Our Ref:

2358.0180002/RWE/AES

Sir:

Transmitted herewith for appropriate action are the following documents:

- 1. Fourth Supplemental Information Disclosure Statement Under 37 C.F.R. § 1.97(b);
- 2. One (1) page of Form PTO/SB/08A citing three (3) documents;
- 3. A copy of one (1) of the cited documents (B1);
- 4. One (1) page of Form PTO/SB/08B citing three (3) documents;
- 5. Copies of the three (3) cited documents (C1-C3); and
- 6. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Sterne, Kessler, Goldstein & Fox PLLC. : 1100 New York Avenue, NW : Washington, DC 20005 : 202.371.2600 f 202.371.2540 : www.skqf.com

Commissioner for Patents July 24, 2006 Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

Sterne, Kessler, Goldstein & Fox P.L.L.C.

Ann E. Summerfield
Attorney for Applicants
Registration No. 47,982

RWE/AES:las Enclosures

561272_1.DOC

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In re application of:

BOYER et al.

Appl. No.: 10/698,928

Filed: October 31, 2003

For: Novel Cytarabine Monophosphate

Prodrugs

Confirmation No.: 2990

Art Unit: 1626

Examiner: T. Solola

Atty. Docket: 2358.0180002/RWE/AES

Fourth Supplemental Information Disclosure Statement Filing Under 37 C.F.R. § 1.97(b)

Mail Stop Amendment

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Forms PTO/SB/08A and PTO/SB/08B are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. This Fourth Supplemental Information Disclosure Statement is a continuation of Applicants' Third Supplemental Information Disclosure Statement filed on June 13, 2006 in connection with the above-captioned application.

Copies of documents **B1** and **C1** to **C3** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), copies of documents **A1** and **A2**, U.S. patents cited on the attached Form PTO/SB/08A, are not submitted.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may

not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.

It is respectfully requested that the Examiner initial and return copies of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

lim & Summifield

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s are required to respond to a collection of information unless it contains a valid OMB control number.

Under the Paperwork Red Stion Act of 1995, Substitute for form 1449/PTO Complete if Known Application Number 10/698,928 FOURTH SUPPLEMENTAL Filing Date October 31, 2003 INFORMATION DISCLOSURE First Named Inventor Serge H. Boyer STATEMENT BY APPLICANT Art Unit 1626 (Use as many sheets as necessary) **Examiner Name** Taofiq A. Solola Attorney Docket Number 2358.0180002/RWE/AES (MTI-046) Sheet of

| | U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|--------------------------|--|-----------------------------|--|--|--|
| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, | |
| | | Number-Kind Code ^{2 (If Known)} | | | Where Relevant Passages or Relevant Figures Appear | |
| | A1 | 5,854,231 | 12-29-1998 | Camden | | |
| | A2 | 6,037,335 | 03-14-2000 | Takashima et al. | | |
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| | B1 | WO 95/07920 | 03-23-1995 | Gilead Sciences | | |
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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| Substitute for form 1449/PTO | C | Complete if Known | | |
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| EQUIPTH CUIDDLE MENTENCE | Application Number | 10/698,928 | | |
| FOURTH SUPPLEMENTA | l Filing Date | October 31, 2003 | | |
| INFORMATION DISCLOS | riist Named Inventor | Serge H. Boyer | | |
| STATEMENT BY APPLICA | 1 /tit Oilit | 1626 | | |
| (Use as many sheets as necessa | Examiner Name | Taofiq A. Solola | | |
| Sheet 1 of 1 | Attorney Docket Number | 2358.0180002/RWE/AES (MTI-046) | | |

| | Non Patent Literature Documents | |
|--|---|---|
| Cite Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), tit | | |
| C1 | BOYER, S. et al., "The Discovery of MB07133: A HepDirect® Prodrug of Cytarabine Monophosphate for the Treatment of Hepatocellular Carcinoma," poster presentation at the American Chemical Society (ACS) Prospective, Boston, MA (May 2006). | |
| C2 | ERION, M. et al., "HepDirect Prodrugs for Targeting Nucleotide-Based Antiviral Drugs to the Liver", Current Opinion in Investigational Drugs 7(2): 109-117, The Thomson Corporation (2006). | |
| С3 | MA, B, et al., "A Phase I/II Study to Assess the Safety, Tolerability and Pharmacokinetics (PK) of Intravenous (IV) Infusion of MB07133 in Subjects with Unresectable Hepatocellular Carcinoma (HCC) (Poster ID 2054, no. 19)," poster presentation at the American Society of Clinical Oncology (ASCO) Conference, Atlanta, Georgia (June 2006). | |
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| | No. 1 C1 C2 | Cite No. Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published BOYER, S. et al., "The Discovery of MB07133: A HepDirect® Prodrug of Cytarabine Monophosphate for the Treatment of Hepatocellular Carcinoma," poster presentation at the American Chemical Society (ACS) Prospective, Boston, MA (May 2006). ERION, M. et al., "HepDirect Prodrugs for Targeting Nucleotide-Based Antiviral Drugs to the Liver", Current Opinion in Investigational Drugs 7(2): 109-117, The Thomson Corporation (2006). MA, B, et al., "A Phase I/II Study to Assess the Safety, Tolerability and Pharmacokinetics (PK) of Intravenous (IV) Infusion of MB07133 in Subjects with Unresectable Hepatocellular Carcinoma (HCC) (Poster ID 2054, no. 19)," poster presentation at the American Society |

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| Examiner | Date | |
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Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.